REMARKS

Claims 1-33 are pending. Claims 29-33 stand withdrawn from consideration as a non-elected invention under a restriction requirement. The provisional election of claims was made with traverse. New claims 34-36 have been added to recite alternative modes of administration. Support for these claims may be found throughout the specification, for example, in the Experimental Procedure, and at pages 12-14. The drawings have been amended to incorporate Figure 1. Support for Figure 1 may be found in Figure 3 of the priority document, U.S. provisional application 60/250,164, and in the specification at page 3, lines 18-23, which provides a brief description of Figure 1. The specification has been amended to delete reference to Figures 2-4 under the heading "Brief Description of the Figures" and incorporate the same information under the heading "Detailed Description." The amendments add no new matter.

Rejection Under 35 U.S.C. § 103

Claims 1-23 stand rejected as being obvious under 35 U.S.C. §103(a) in view of Nelson (U.S.P.N. 4,323,558) and Boltralik (U.S.P.N. 5,420,120). The Office Action asserts that Nelson teaches the use of triethylenetetramine, a copper chelator, for treating inflammation, and that Boltralik teaches the use of glucocorticoid anti-inflammatory compounds for treating dermatological and ophthalmic inflammation caused by laser irradiation. The Office Action asserts that it would therefore have been obvious to a skilled person to use the claimed compounds for treating inflammation of the eye due to Boltralik's teaching that "compounds which have been used for the treatment of inflammation of a different part of the body, can also be used for the treatment of ocular inflammation." Furthermore, the Office Action asserts that no evidence to establish the unexpected or unobvious nature of the claimed invention has been presented.

This rejection is respectfully traversed. The test for obviousness requires the establishment of three basic criteria, as follows:

> First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. (emphasis added) (M.P.E.P § 2143)

This test has not been met in the present case. Nelson teaches the use of triethylenetetramine to treat inflammation of the skin. Nelson therefore does not teach or suggest the claimed invention, which is directed to the use of a copper chelator for treating inflammation in the eye. Boltralik discloses the use of a different class of compounds, glucocorticoid derivatives, for treating ocular inflammation. Thus, Boltralik does not remedy Nelson's lack, and a skilled person would find no motivation to combine the references.

Furthermore, neither the cited references nor the prior art in general provide a reasonable expectation of success for specifically using a copper chelator to treat ocular inflammation. Anti-inflammatory agents constitute a very large and diverse class of compounds, all of which may not be suitable for administration to the eye. For example, Boltralik also discloses that one of the side effects of anti-inflammatory steroids is the elevation of intraocular pressure. Similarly, prior to the filing date of the invention, it was known that numerous systemic drugs produce adverse effects that involve the eye (see, for example, Jaanus SD, Optom Clin. 2:73-96, 1992, "Exhibit A," Moorthy RS and S Valluri, Curr Opin Ophthalmol. 10:438-46, 1999, "Exhibit B," Abstracts only, enclosed herewith). In an attempt to make such information publicly available, the National Registry of Drug-Induced Ocular Side Effects (Portland, Oregon) maintains a database of drug information on ocular toxicology (Fraunfelder FT and SM Meyer, The national registry of drug-induced ocular side effects, Aust J Ophthalmol. 12(2):129-31,1984, "Exhibit C," Abstract only, enclosed herewith) and points to cyclosporine, an anti-inflammatory agent, as being linked to visual complications including severe ocular pain, visual hallucinations, etc. Furthermore, while a large number of non-steroidal anti-inflammatory drugs (NSAIDs) have been approved for systemic use, only 4 NSAIDs have been approved for use in ophthalmic

conditions (see, for example, the results of the "Drug Search" for anti-inflammatory drugs on www.mayoclinic.com, "Exhibit D," enclosed herewith). Thus, a skilled person would have no reason to conclude from the literature or from common knowledge that a particular compound, previously used systemically, was likely to be efficacious in treating ocular inflammation.

Accordingly, in view of the absence of any suggestion or motivation to combine the references and due to the lack of any reasonable expectation of success from the prior art, the applicant respectfully submits that the claimed invention is not obvious over the combination of Nelson and Boltralik, and that no evidence of unexpected results is necessary in this case to support a conclusion of non-obviousness. Withdrawal of the rejection is requested.

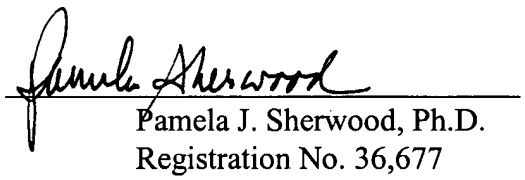
CONCLUSION

Applicants submit that all of the claims are now in condition for allowance, which action is requested. If the Examiner finds that a Telephone Conference would expedite the prosecution of this application, she is invited to telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any other fees under 37 C.F.R. §§ 1.16 and 1.17 which may be required by this paper, or to credit any overpayment, to Deposit Account No. 50-0815, order number SMAR-019.

Respectfully submitted,

Date: August 19, 2003

By: 

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